UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DEPOMED, INC., Plaintiff, v. ACTAVIS ELIZABETH LLC et al., Defendants.	C.A. No. 3:12-cv-01358-JAP-TJB
DEPOMED, INC., Plaintiff, v. ZYDUS PHARMACEUTICALS (USA), INC. et al., Defendants.	C.A. No. 3:12-cv-02813-JAP-TJB (Consolidated for Pretrial Purposes)

DEFENDANTS' JOINT OPENING *MARKMAN* BRIEF

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Table of Abbreviations

Abbreviation	Term
Actavis	Defendants Actavis Elizabeth LLC and Actavis, Inc.
Incepta	Defendants Incepta Pharmaceuticals Co. Ltd. and Abon Pharmaceuticals, LLC
Zydus	Defendants Zydus Pharmaceuticals (USA), Inc., and Cadila Healthcare Ltd.
Defendants	Actavis, Incepta and Zydus, collectively
Depomed	Plaintiff Depomed, Inc.
Parties	Plaintiff and Defendants
Ex. X	Exhibit No. X attached to the Affidavit of Jason T. Murata filed concurrently with this brief.
Lowman Decl.	Declaration of Dr. Lowman in Support of Defendants' Opening Markman Brief, filed with this brief.
XX:YY	Refers to column XX and line YY of a patent
'475 patent	U.S. Patent No. 6,340,475 (Ex. 1)
'962 patent	U.S. Patent No. 6,488,962 (Ex. 2)
'280 patent	U.S. Patent No. 6,635,280 (Ex. 3)
'927 patent	U.S. Patent No. 7,438,927 (Ex. 4)
'989 patent	U.S. Patent No. 7,731,989 (Ex. 5)
'756 patent	U.S. Patent No. 8,192,756 (Ex. 6)
'332 patent	U.S. Patent No. 8,252,332 (Ex. 7)
patents-in-suit	U.S. Patent Nos. 6,340,475, 6,488,962, 6,635,280, 7,438,927, 7,731,989, 8,192,756 and 8,252,332, collectively
'475 patent family	The '475 and '280 patents. These patents are based on the same patent application, U.S. Pat. App. No. 08/870,509, and they share substantially the same disclosure. Thus, consistent with the Court's practice in its prior claim construction order relating to these patents, citations to the specifications of these patents will be only to the '475 patent with the understanding that those cited portions of the '475 patent also appear in the '280 patent, unless otherwise noted.

Abbreviation	Term
'927 patent family	The '927, '989, '332 and '756 patents. These patents are based on the same patent application, U.S. Patent App. No. 10/208,309, and they share substantially the same disclosure. Thus, consistent with the Court's practice in its prior claim construction order relating to these patents, citations to the specifications of these patents will be only to the '927 patent with the understanding that those cited portions of the '927 patent also appear in the other three related patents, unless otherwise noted.
FDA	U.S. Food & Drug Administration
NDA	New Drug Application
ANDA	Abbreviated New Drug Application
Orange Book	FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations"
PTO	United States Patent and Trademark Office
Sun case	Depomed Inc. et al. v. Sun Pharma Global FZE et al., No. 3:11-cv-03553-JAP-TJB (D.N.J.) (Pisano, J.); the Sun case involved different parties from the present case, and a different drug product (Glumetza – metformin HCl).
Lupin case	Depomed, Inc. v. Lupin Pharms., Inc., No. 4:09-cv-5587-PJH (N.D. Cal.) (Hamilton, J.); the Lupin case involved different parties from the present case, and a different drug product (Glumetza – metformin HCl).
Ivax case	Depomed, Inc. v. Ivax Corp. et al., No. 3:06-cv-00100-CRB (N.D. Cal.) (Breyer, J.); the Ivax case involved different parties from the present case, and a different drug product (Glucophage XR – metformin HCl).
Sun Markman Order	Memorandum Opinion dated Aug. 3, 2012, Depomed, Inc. et al. v. Sun Pharma Global FZE et al., No. 3:11-cv-03553-JAP-TJB (D.N.J.) (Pisano, J.) (D.I. 66) (Ex. 15)
Lupin Markman Order	Order Construing Claims dated May 17, 2011, Depomed, Inc. v. Lupin Pharms, Inc., No. 4:09-cv-5587-PJH (N.D. Cal.) (Hamilton, J.) (D.I. 107) (Ex. 14)
Ivax Markman Order	Order dated Dec. 20, 2006, Depomed, Inc. v. Ivax Corp., No. 3:06-cv-00100-CRB (N.D. Cal.) (Breyer, J.) (D.I. 76) (Ex. 22)

INTRODUCTION

Defendants seek approval to sell generic gabapentin once-daily tablets. Gabapentin is a drug product that has been commercially available since the 1990s. In its once-daily form, it is indicated for the management of postherpetic neuralgia. Depomed is the NDA holder for gabapentin once-daily tablets, which it sells under the trade name Gralise®. In FDA's Orange Book entry for Gralise®, Depomed has listed eight patents. Depomed has asserted 118 patent claims from seven of these patents against the Defendants in this action.[1]

Because Depomed asserted a large number of patents and claims, there are a correspondingly large number of claim construction disputes. (See ECF No. 128-1, Ex. B (Ex. 21[2]).) Defendants have tried to address disputed terms together where similar issues are raised, and have thereby divided the 24 disputed claim terms into nine groups. (See Ex. 11; Ex. 21 at Ex. B.) A detailed listing of the nine groups of disputed terms is set forth as Exhibit 11.

Defendants' proposed constructions clarify the meaning of the disputed terms consistent with the intrinsic record – i.e., the patent claims, specification and prosecution history. Depomed's proposed constructions, by contrast, depart from the intrinsic record and selectively omit claim limitations or leave their meaning ambiguous, which will undoubtedly lead to future disputes over the meanings of those terms. Accordingly, the Court should adopt the Defendants' proposed claim constructions.

The Parties have agreed on the meaning of a number of terms recited by the claims, and

[1] Some of the claims have been asserted against fewer than all Defendants. To the extent any disputed claim term is only found in claims not asserted against a defendant, that defendant takes no position with respect to that claim term.

[2] As set forth in the Table of Abbreviations, "Ex. X" refers to Exhibit No. X attached to the Affidavit of Jason T. Murata filed concurrently with this brief.

Defendants request that the Court adopt these agreed-upon definitions, set forth in Exhibit 10.

FACTUAL BACKGROUND

1. GABAPENTIN

The active ingredient of the products at issue, gabapentin, is not new. Gabapentin was originally approved by the FDA on December 30, 1993 as adjunctive therapy in the treatment of partial seizures and marketed by Pfizer (and its predecessor Parke-Davis) under the name Neurontin®. (See Ex. 8; '927 patent, 1:12-25.) In May 2002, Neurontin® was approved by FDA for the management of postherpetic neuralgia in adults. (See Exs. 9 and 20.)

2. THE PATENTS-IN-SUIT

A. The '475, '280 and '962 Patents

The '475 and '280 patents relate to oral dosage forms designed for gastric retention and controlled delivery of a drug into the stomach, and the '962 patent relates to tablet shapes designed to enhance gastric retention of oral dosage forms. This Court has previously construed certain terms in these patents. (See generally Ex. 15.) The patents are described in more detail in the claim construction opinions in the Sun, Ivax and Lupin cases. (Exs. 15, 22, 14.)

B. The '927, '989, '756 and '332 Patents

These patents purport to describe gastric retained dosage forms containing gabapentin. According to these patents, by extending the time period for which the gabapentin dosage form is retained in the stomach, the prolonged duration of the transit time provides for improved gabapentin absorption because gabapentin is known to be absorbed in the upper, but not the lower, gastrointestinal tract. (See, e.g., '927 patent, 1:25-36, 2:14-25.) The patents are also directed to methods of treating conditions specifically treated by gabapentin – epilepsy and neuropathic pain – using the gastric retained dosage forms. (See id. at 1:54-64.)

ARGUMENT

1. LAW OF CLAIM CONSTRUCTION

The Court is familiar with the law governing claim construction. (See, e.g., Ex. 15.) Therefore, the legal principles governing Defendants' claim constructions are recited in the context of the specific terms being construed.

As set forth in detail below, Defendants' proffered constructions adhere to the Federal Circuit's longstanding maxim that, for purposes of claim construction, the specification is usually "dispositive," and is, without question, the "single best guide" to the meaning of the terms in dispute. Phillips v. AWH Corp., 415 F.3d 1303, 1314-15 (Fed. Cir. 2005) (en banc) (citations omitted). Defendants' proposed constructions also adhere to the principle that the prosecution history should also be consulted because it evidences how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be. Id. at 1317. Other claim construction tools particularly germane to the present issues include:

- "[C]laims are interpreted with an eye toward giving effect to all terms in the claim." Bicon, Inc. v. Straumann Co., 441 F.3d 945, 950 (Fed. Cir. 2006) (citations omitted). The construction must not treat any claim language as meaningless or "mere surplusage." Texas Instruments Inc. v. U.S. Int'l Trade Comm'n, 988 F.2d 1165, 1171 (Fed. Cir. 1993).

- The primary purpose of claim construction is to "resol[ve] disputed meanings and technical scope, [and] to clarify and when necessary to explain what the patentee covered by the claims." U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997).

2. "ADMINISTRATION" AND "ADMINISTERING" IN THE '927, '989, '756 AND '332 PATENTS[3]

Term Nos.[4]	Claim Language	Defendants' Proposed Construction	Depomed's Proposed Construction
32, 37, 38, 39, 49	*administration*[5]	"*providing [of a drug substance] to the body of a patient or mammal*"	Plain and ordinary meaning; does not require construction
33	wherein the dosage form provides *administration* of at least 80 wt% of the gabapentin to be delivered over a period of about 5-12 hours	"wherein the dosage form *provides to the body of the mammal* at least 80 wt% of the gabapentin to be delivered over a period of about 5-12 hours"	
34	wherein the *administering* achieves a reduced incidence of side effects to the central nervous system, relative to a non-gastric retained dosage form	"wherein *the providing [of the drug substance] to the body of the mammal* achieves a reduced incidence of side effects to the central nervous system, relative to a non-gastric retained dosage form"	

The Parties' dispute centers on whether or not "administration" and "administering" require that the drug-containing dosage form be provided to the body of a patient or mammal.[6] (Lowman Decl. ¶ 16.)

The context of the claims provides compelling evidence that "administration" and

[3] These disputed claims terms can be found in: claims 17-19, 23, 25, 26, 30, 32-35, 39-43, 45, 49, 50, 52, 53, 55, 56, 59 and 61-63 of the '927 patent; claims 1-7, 10-15, 19 and 20 of the '989 patent; claims 1-12, 15 and 16 of the '756 patent; and claim 19 of the '332 patent.

[4] "Term Nos." are from the Joint Claim Construction and Prehearing Statement, ECF No. 128-1, Ex. B. (Ex. 21 at Ex. B.)

[5] For Term Nos. 37-39 and 49, the term "administration" is contained in a longer claim term. For brevity, Defendants have only included the disputed term in this table.

[6] Defendants' proposed constructions for term nos. 33 and 34 refer only to a "mammal" because the relevant claims refer specifically to a "mammal." The differences in the proposed constructions for Term Nos. 33 and 34, however, do not present substantially different issues from Term Nos. 32, 37-39 and 49.

"administering"[7] require that the claimed dosage form be provided to the body of a patient or mammal. Some claims explicitly state that the drug is administered to a mammal. (See, e.g., '927 patent, 12:37-42, 13:25-30; Lowman Decl. ¶ 17.) Even in claims that do not explicitly state that the dosage form is administered to a patient or mammal, providing it to the body of a patient or mammal, e.g., swallowing the dosage form, is clear from the remainder of the context. (Lowman Decl. ¶¶ 17-18.)

For example:

- Asserted claims of the '989 patent recite a polymer matrix that swells "to increase its size to promote gastric retention of the dosage form in a stomach in a fed mode." (See, e.g., '989 patent, 12:9-18.) The reference to a "stomach" obviously requires the dosage form to be introduced into the body of a patient or mammal.

- Independent claim 6 of the '756 patent is similarly directed to a "method of treating a condition responsive to a therapeutic dose of gabapentin," which only makes sense if the gabapentin is provided to a patient or mammal. ('756 patent, 13:14-15.)

- Independent claims 1, 6 and 15 of the '756 patent also each use the term "administration" in connection with "once-daily or twice daily ingestion of the dosage form," (id. at 12:58-59, 13:25-26, 14:26-27), again confirming that the term means that the "administration" involves a patient or mammal being provided with the dosage form.

- Claim 19 of the '332 patent depends from claim 1, which refers to ingestion of the dosage form and recites particular differences in the maximum plasma concentrations of drug in the body, which again implicitly calls for a patient or mammalian subject to which the dosage form is provided. (See '332 patent, 12:12-22, 13:11-13.)

(Id.) Thus, the context of the claims makes clear that "administration" and "administering" means "providing [of the drug substance] to the body of a patient or mammal." See Phillips, 415 F.3d at 1314 ("the context in which a term is used in the asserted claim can be highly

[7] And related terms, such as "administered."

instructive").

The specification similarly describes "administration" and "administering" as providing the drug substance to the body of a patient or mammal. (Lowman Decl. ¶ 19.) For example, the specification states:

- "*administering* . . . gabapentin . . . in a gastric retained dosage form to a *mammal*" and "*administering* a therapeutically effective amount of gabapentin to a *patient* in need thereof" ('927 patent, 1:60-67 (emphasis added));
- "[f]or purposes of facilitating *patient* compliance, *administration* of any of the aforementioned additional agents at the same time is preferred" (id. at 5:46-48 (emphasis added)); and
- "*gastric retained* dosage form of gabapentin is an extended release oral drug dosage form for releasing gabapentin into the *stomach*, duodenum and small intestine of a *patient*." (Id. at 6:50-53 (emphasis added).)

The specification thus repeatedly states that the claimed dosage form is to be provided to a patient or a mammal. This makes sense – the claimed subject matter is a pharmaceutical dosage form, which only has utility when provided to the body of patients or mammals. (Lowman Decl. ¶ 19.)

Where the specification does not specifically refer to patients or mammals, the context makes clear that the dosage form is being provided to patients or mammals. (Lowman Decl. ¶ 20.) As with the claims, the specification states that the drug should be administered "with the morning or evening meals" ('927 patent, 5:19-26), and that the dosage form can be administered to treat various conditions or disease states. (Id. at 2:30-44, 2:50-62, 4:46-63.) Again, these concepts only make sense in the context of providing the dosage form to the body of a patient or mammal – as the specification explicitly acknowledges with respect to treating conditions or disease states. (Id. at 2:34-36 ("'treating' covers treating the specified disease in a mammal, particularly a human"); Lowman Decl. ¶ 20.)

The relevant prosecution history of the '927 patent family further confirms that the patentee used the terms to refer to providing of the dosage form or drug substance to a patient or mammal. (See, e.g., Ex. 13 at 8 (patentee argued that "[t]he ordinarily skilled artisan readily understands that the term C_{max} refers to the maximum *plasma concentration* of an *administered* drug") (emphasis added); Lowman Decl. ¶ 21.)

By asserting that no construction is needed, Depomed would leave the metes and bounds of the claim unclear if the dosage form need not be administered to the body of a patient or mammal so that the drug gets into the body's bloodstream. See Tyco Healthcare Grp. LP v. Mut. Pharm. Co., No. 07-1299, 2009 WL 44745, at *4 (D.N.J. Jan. 5, 2009) (declining to adopt plaintiff's construction because "it would replace clarity with ambiguity, defeating the purpose of claim construction"). Depomed's proposed construction should thus be rejected.

3. "REMAINS SUBSTANTIALLY INTACT" IN THE '475 AND '280 PATENTS[8]

Term No.	Claim Language	Defendants' Proposed Construction	Depomed's Proposed Construction
19	and that remains substantially intact	"remains substantially intact" means "a polymeric matrix in which the polymer portion substantially retains its size and shape *after ingestion* without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or *small particles*"	A polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or *small pieces*

The two differences between the Parties' constructions are indicated in italics in the above table.

[8] This disputed claim term is found in claims 1, 8-15, 61 and 62 of the '475 patent and claims 1, 8-15, 45 and 46 of the '280 patent.

A. "After Ingestion"

One of the primary goals of the '475 and '280 patents is to "extend the time of delivery into the stomach of drugs." ('475 patent, 1:18-19; Lowman Decl. ¶ 24.) That the claimed dosage form remains "substantially intact" after ingestion is an important aspect to satisfying this goal. The specification explains that when the stomach is in the fed mode:

> Contractions of the stomach result in a sieving process that allows liquids and small particles to pass through a partially open pylorus. Indigestible particles greater than the size of the pylorus are retropelled and retained in the stomach. Particles exceeding about 1 cm in size are thus retained in the stomach for approximately 4 to 6 hours. The dosage form of the present invention is designed to achieve the minimal size through swelling following ingestion during the fed mode.

('475 patent, 11:53-12:4.) According to the specification, a dosage form that does not remain substantially intact after ingestion would not meet the 1 cm size necessary to be retained in the stomach. (Lowman Decl. ¶ 24.)

To ensure that the dosage form is gastric retained, the specification explains that the matrix is "solid prior to administration and, once administered, remains undissolved in (i.e., is not eroded by) the gastric fluid for a period of time sufficient to permit the majority of the drug to be released by the solution diffusion process during the fed mode." ('475 patent, 6:9-14.) Thus, the specification explains that, if the dosage form dissolves in or is eroded by the gastric fluid, it will not remain in the stomach long enough to have the drug released in the stomach in the fed mode. (Lowman Decl. ¶ 25.)

It is against this backdrop that the patentee explained what it meant by "substantially intact" in the specification of the '475 patent:

> In all cases . . . the drug will be substantially all released from the matrix within about ten hours, and preferably within about eight hours, *after ingestion*, and the polymeric matrix will remain *substantially intact* until all of the drug is released. The term "substantially intact" is used herein to denote a polymeric matrix in which the polymer portion substantially retains its size and shape without

> deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles.

(See '475 patent, 9:32-41 (emphasis added).) Taken in context, this passage underscores that the polymeric matrix must retain its size and shape after ingestion of the dosage form. (Lowman Decl. ¶ 26.) Otherwise, remaining substantially intact serves no purpose. The mere fact that the dosage form is intact before ingestion does nothing to ensure that it is retained in the stomach of the mammal or patient. (Id.) It is only when it is intact and swollen *after ingestion* that the claimed dosage form is purportedly retained in the stomach to extend the time period over which the drug is released. See Trading Techs. Int'l, Inc. v. ESpeed, Inc., 595 F.3d 1340, 1353-54 (Fed. Cir. 2010) (affirmed claim construction that adopted definition from specification but added the word "manual" because specification "strongly suggest[ed]" requirement of manual input, and allowing automatic changes to input would defy invention's goal).

B. "Particles"

The Parties' proposed constructions also differ with respect to the use of the word "particles" by Defendants and "pieces" by Depomed. "Particles" is the term the patentee specifically chose when it explained what is meant by a polymeric matrix that remains "substantially intact." ('475 patent, 9:36-41.) "Pieces," on the other hand, is not found anywhere in the specification or claims. There is no principled reason to replace a word specifically used by the patentee with a different word that has no support anywhere in the intrinsic evidence. (Lowman Decl. ¶¶ 27-28.)

4. "DIMENSIONALLY UNRESTRICTED" AND "DIMENSIONALLY UNRESTRAINED" IN THE '280, '962, '927, '989 AND '756 PATENTS[9]

Term No.	Claim Language	Defendants' Proposed Construction	Depomed's Proposed Construction
8	said dosage form being one that when swollen in a *dimensionally unrestricted manner* as a result of imbibition of water	"said dosage form being one that upon imbibition of water swells in a *physically unlimited manner in all dimensions*"	Adopt Judge Pisano's construction in Depomed Inc. et al. v. Sun Pharma Global FZE, et al., No. 3:11-cv-03553-JAP-TJB
9	said matrix being one that swells in *an unrestricted manner* along both such axes upon imbibition of water	"said matrix being one that swells in a *physically unlimited manner* along the two orthogonal axes upon imbibition of water"	Adopt Judge Pisano's construction in Depomed Inc. et al. v. Sun Pharma Global FZE, et al., No. 3:11-cv-03553-JAP-TJB
10	swells in a dimensionally unrestrained manner by imbibing water	"swells in a *physically unlimited manner in all dimensions* upon imbibition of water"	Adopt Judge Pisano's construction for "when swollen in a dimensionally unrestrained manner as a result of imbibition of water" in Depomed Inc. et al. v. Sun Pharma Global FZE, et al., No. 3:11-cv-03553-JAP-TJB
11	swells unrestrained dimensionally by imbibing water		

The principal dispute appears to be whether the Court should adopt the incomplete prior construction that was agreed upon by the parties in the Sun case, which construction renders the "dimensionally unrestricted" claim limitation meaningless.

A. Judge Hamilton's Incomplete Construction Renders the Claim Term Meaningless

A longer phrase containing the term "dimensionally unrestricted" was construed by Judge Hamilton in the Lupin case. The Lupin construction was subsequently adopted by agreement of the parties in the Sun case. (Ex. 15 at 15.) In the Lupin case, the court construed

[9] These disputed claim terms are found in claims: 1, 8-15, 45 and 46 of the '280 patent; claims 1, 2 and 5-16 of the '962 patent; claims 17-19, 23, 25, 26, 30, 32-35, 39-43, 45, 50, 53, 52, 55, 56, 59 and 61-63 of the '927 patent; claims 1-7, 10-15, 19 and 20 of the '989 patent; and claims 1-12, 15 and 16 of the '756 patent.

"said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode" in the '475 patent and "said dosage form being one that when *swollen in a dimensionally unrestricted manner* as a result of imbibition of water is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during the fed mode" in the '280 patent. (Ex. 14 at 12, ll. 7-15 (emphasis added).) Because the parties in both the Lupin and Sun cases agreed that the terms should have the same meaning, both of these phrases were given the same meaning even though they contain different language.

The prior construction of the phrase, however, omits the "swollen in a dimensionally unrestricted manner" limitation in claim 1 of the '280 patent. Judge Hamilton noted that this phrase was a significant difference between the disputed claim terms in the '280 and '475 patents, stating:

> However, Claim 1 of the '280 patent (the claim where the word 'unrestricted' appears) refers to the dosage form being swollen in a 'dimensionally unrestricted' manner. It is not the swelling itself that is unrestricted, but the swelling of the dimensions of the dosage form – that is, length, the width, or other dimension of the dosage form – based on the swelling characteristics of the selected polymer.

(Ex. 14 at 10, ll. 1-7.) She went on to acknowledge that "[b]ecause Claim 1 of the '280 patent contains the express language 'when swollen in a dimensionally unrestricted manner,' the dosage form in Claim 1 of the '280 patent must be in a state where it has swollen in all dimensions." (Id at 10, ll. 20-22.) This difference, however, did not find its way into the adopted construction.

Defendants' proposed construction follows Judge Hamilton's claim constructions from the Lupin case and further includes her remarks concerning "dimensionally unrestricted manner," which ensures that all claim terms are given meaning. Bicon, 441 F.3d at 950-51 ("[C]laims are interpreted with an eye toward giving effect to all terms in the claim," and

adopting a construction that reads a limitation out of the claim is "contrary to the principle that claim language should not [be] treated as meaningless").

B. Defendants' Proposed Construction is Supported by the Intrinsic Evidence and, in Particular, the Prosecution History

Defendants' proposed construction is also supported by the intrinsic evidence. Each of the asserted patents discloses dosage forms that swell in a dimensionally unrestricted manner. (See, e.g., '280 patent, 7:54-57 ("The water-swellable polymer forming the matrix in accordance with this invention is any polymer . . . that swells in a dimensionally unrestricted manner."); '962 patent, 4:48-51 ("Water-swellable polymers useful in the preparation of the dosage form of this invention include polymers . . . that swell in a dimensionally unrestricted manner upon imbibition of water and hence of gastric fluid."); '927 patent, 6:50-59; Lowman Decl. ¶ 31.) The matrix swells in a physically unlimited manner along both orthogonal axes so that the matrix is allowed to expand in each direction. (See, e.g., '962 patent, 4:22-47; Lowman Decl. ¶ 31.) The specifications disclose that swelling in all directions without physical restriction enables the dosage form to expand so that it does not escape the stomach through the pylorus. (See generally '962 patent, 3:22-41; '280 patent, 12:3-5; '927 patent, 6:56-59.) Physical limitations in any dimension on such swelling would thus be contrary to the specification's stated goal of ensuring gastric retention of the dosage form. (Lowman Decl. ¶ 31.)

The prosecution histories of the relevant patents also make clear that the patentee believed that its dosage form must be able to swell without physical limitation in any dimension. During the prosecution of the '962 patent, for example, the Examiner rejected the claims as anticipated by and/or obvious in view of U.S. Patent No. 6,120,803 ("Wong") (Ex. 17). (See Ex. 16a at 2, 4; Lowman Decl. ¶ 32.) Wong described a dosage form that had a band around it that restricted swelling in certain dimensions as illustrated in the following image:

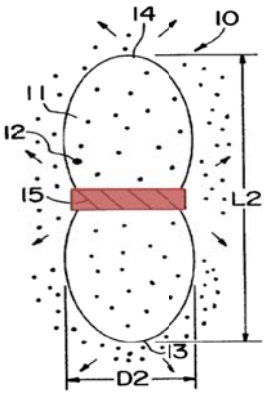

Figure 2 from Wong:

This figure illustrates the swollen Wong dosage form with a band (labeled number 15 and shaded red) that restricts swelling in certain directions. (See generally Ex. 17, 11:30-12:8 and 14:15-46 (Wong) (red shading added).)

(Lowman Decl. ¶ 32.)

The patentee argued that the claimed subject matter was distinguishable from Wong because, among other things:

> a critical feature of the present invention is that the tablet must be allowed to swell in *all* directions, and particularly in the lateral direction (i.e., along its shorter dimension) so that it can no longer slip through the pylorus even if the tablet happens to be oriented in alignment with the pyloric axis.

(Ex. 16b at 2 (emphasis in original); Lowman Decl. ¶ 33.)

The patentee more specifically explained the differences between Wong and the claims in a later amendment:

> Wong et al. address the problem of how to prolong the retention of a swellable tablet in the stomach by incorporating a rigid, ***constraining secondary matrix*** into the structure of the tablet. On the other hand, the Applicants rely solely on the ***unrestricted swelling*** of a ***monolithic*** polymer matrix to maintain the tablet in the stomach for prolonged periods of time . . . Applicants' tablet is free to swell in an unrestricted manner, whereas the tablet of the Wong et al. disclosure is constrained so that swellability of the tablet is limited.
>
> . . . The ***dimensionally unrestricted*** swelling of the tablet which occurs when the tablet contacts the aqueous environment of the stomach is responsible for retention of the tablet in the stomach. The ***dimensionally unrestricted*** swelling of the tablet creates in an entity that is too large to escape the confines of the stomach by slipping through the pyloric sphincter, and thus, provides the mechanism by which the tablet is retained within the stomach. Hence, unrestricted swellability is ***essential*** to the Applicants' invention.

(Ex. 16c at 3-4 (emphasis in original); Lowman Decl. ¶ 34.)

The patentee further explained that "***the concept of constrained swelling*** which is the basis for creation of [the Wong] tablet ***is diametrically opposed to the concept of dimensionally unrestricted swelling*** which is the basis for the creation of the Applicants' invention." (Ex. 16c at 5 (emphasis in original); Lowman Decl. ¶ 34.) Based on the arguments made during prosecution, physically unrestricted swelling should be incorporated into the construction of these claim terms. See Phillips, 415 F.3d at 1317 ("the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be").

Similarly, during the prosecution of the '927 patent, the patentee contrasted a prior art dosage form disclosed in U.S. Patent No. 5,906,832 ("Jao") with the claimed dosage form. (Lowman Decl. ¶ 35.) The patentee argued that the prior art utilizes "a hard outer capsule for retaining the original shape of the dosage form," and thus "*maintains its integrity* during transit in the GI tract," whereas the claimed dosage forms "swell[] in a *dimensionally unrestrained manner* to achieve retention in the stomach, for release of drug in the stomach." (Ex. 12b at 19 (emphasis added); Lowman Decl. ¶ 35.)

This argument was later reiterated by the patentee during prosecution of the '756 patent: "the dosage form of Jao *retains its external shape* during transit through the GI tract, and is not designed to swell, and moreover to *swell unrestrained dimensionally*, to achieve an increase in size which promotes gastric retention." (Ex. 13 at 10 (emphasis added); Lowman Decl. ¶ 36.) Thus, the patentee has repeatedly made clear that its claimed dosage forms cannot have any physical restraint in the ability to swell. Defendants' proposed construction reflects the patentee's clear and repeated statements to this effect. (See Lowman Decl. ¶¶ 32-36.)

Depomed argues that the Court should adopt the prior construction to which the parties stipulated in the Sun case based on Judge Hamilton's claim construction in the Lupin case. As explained above, however, the construction improperly reads out the "dimensionally unrestricted" and "dimensionally unrestrained" swelling language of asserted claims of the '280, '962, '927 and '989 patents. See Bicon, 441 F.3d at 951. And, Defendants' proposed construction more fully captures Judge Hamilton's opinions, including Judge Hamilton's observation that the claimed dosage form must be in a state where it has swollen in all dimensions. (See Ex. 14 at 10, ll. 1-7, 20-24.) Depomed's proposed construction should thus be rejected.

5. "GASTRIC RETENTION" AND "RETENTION IN THE STOMACH" IN THE '475, '280, '927, '989 AND '756 PATENTS[10]

Term No.	Claim Language	Defendants' Proposed Construction	Depomed's Proposed Construction
4	Dispersed in a *gastric retained* dosage form	"contained in a dosage form that allows for extended release of drug substance in the stomach for the duration of drug delivery independent of the intake of food"	Plain and ordinary meaning; does not require construction
12	thereby attaining a size large enough to promote *retention in the stomach* during said fed mode	"such that when the dosage form is introduced into the stomach in the fed mode, it attains a size such that the dosage form remains in the stomach for the duration of drug delivery"	Adopt Judge Pisano's construction in Depomed Inc. et al. v. Sun Pharma Global FZE, et al., No. 3:11-cv-03553-JAP-TJB

[10] These disputed claim terms are found in: claims 1, 8-15, 61 and 62 of the '475 patent; claims 1, 8-15, 45 and 46 of the '280 patent; claims 17-19, 23, 25, 26, 30, 32-35, 39-43, 45, 50, 52, 53, 55, 56, 59 and 61-63 of the '927 patent; claims 1-7, 10-15, 19 and 20 of the '989 patent; and claims 1-12, 15 and 16 of the '756 patent.

Term No.	Claim Language	Defendants' Proposed Construction	Depomed's Proposed Construction
13	is of a size exceeding the pyloric [diameter in the fed mode to promote *retention in the stomach* during said fed mode][11]	"is of a size exceeding the pyloric diameter in the fed mode such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for the duration of drug delivery"	Adopt Judge Pisano's construction in Depomed Inc. et al. v. Sun Pharma Global FZE, et al., No. 3:11-cv-03553-JAP-TJB
14	to increase its size to promote *gastric retention* of the dosage form in the stomach of the mammal	"to increase in size to allow for extended release of drug substance in the stomach of a mammal for the duration of drug delivery independent of the intake of food"	Adopt Judge Pisano's construction for "attaining a size large enough to promote retention in the stomach" in Depomed Inc. et al. v. Sun Pharma Global FZE, et al., No. 3:11-cv-03553-JAP-TJB
15	increase its size to promote *gastric retention* of the dosage form in a stomach in a fed mode	"is of a size exceeding the pyloric diameter in the fed mode such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for the duration of drug delivery"	Adopt Judge Pisano's construction in Depomed Inc. et al. v. Sun Pharma Global FZE, et al., No. 3:11-cv-03553-JAP-TJB
16	to increase its size to promote *gastric retention* of the dosage form in the stomach in a fed mode		

There are two issues for the Court to resolve. First, Defendants seek clarification that the swollen dosage form must be retained in the stomach for the duration of drug delivery. (See Lowman Decl. ¶ 40.) Second, relative to claim terms 4 and 14, Defendants seek clarification that the retention in the stomach is not tied to induction of the fed mode. (See id.)

A. Duration of Gastric Retention

There is no dispute between the Parties that, when swollen in the stomach, the claimed dosage form must be retained in the stomach for some period of time. The dispute between the

[11] The Joint Claim Construction and Prehearing Statement includes a typographical error omitting the bracketed text.

Parties is the duration for which the swollen dosage form must be retained in the stomach.

Judge Hamilton previously construed the longer phrases "said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode" and "said dosage form being one that when swollen in a dimensionally unrestricted manner as a result of imbibition of water is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during the fed mode" to mean "the dosage form, which comprises a polymeric matrix, increases in size due to the ingress of water, such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours." (Ex. 14 at 12, ll. 7-15; Lowman Decl. ¶ 41.) The parties in the Sun case stipulated to the Lupin construction, and it was adopted by the Court. (Ex. 15 at 15 (citing Markman Hearing Tr. 40:6-15).) Although Judge Hamilton construed the phrase to require that the claimed dosage form remain in the stomach "for several hours," there is no explanation of the basis for this part of the construction in Judge Hamilton's opinion. In fact, neither the Lupin parties nor the Sun parties submitted any briefing or arguments to the court regarding this specific issue. (See generally Exs. 23 & 24.) "Several hours" is vague (Lowman Decl. ¶ 41) and fails to provide reasonable guidance to a fact finder as to the duration for which the swollen dosage form must be retained in the stomach. See U.S. Surgical, 103 F.3d at 1568. As such, further construction of this claim term is required.

The purpose of the alleged invention is to have the drug released in the stomach over a prolonged period of time. (Lowman Decl. ¶ 42.) For example, the specification of the '475 patent family states that the alleged invention:

> is in the general field of pharmacology, and relates in particular to formulations for drugs that benefit from a prolonged time of controlled release in the stomach and upper gastrointestinal (GI) tract, and from an enhanced opportunity of absorption in the stomach and upper GI tract rather than the lower portions of the

GI tract.

('475 patent, 1:11-17.) For drugs that are known to have an absorption window high in the GI tract, for example, the claimed dosage form and delivery system is said to maximize the absorption of such drugs by "confining drug delivery to the stomach." (Id. at 3:37-41.)

The specification further explains:

> For drugs of any level of solubility, *the retention of the drug in a tablet or other dosage form beyond the duration of the fed mode raises a number of problems* that detract from the therapeutic efficacy of the drug. These problems arise from the tendency of the tablet when the patient is no longer in the fed mode to pass from the stomach into the small intestine, and over a period of 2-4 hours to pass through the small intestine, thus reaching the colon with the drug still in the tablet. This loss of effectiveness occurs with drugs that provide their maximum benefit with minimum side effects when absorbed in the stomach and upper GI tract rather than the colon. The reasons are either favorable conditions in the stomach, unfavorable conditions in the colon, or both.

(Id. at 2:21-33 (emphasis added).) Thus, the specification explains that it is problematic from a therapeutic perspective for drug to remain in the dosage form after it leaves the stomach. (Lowman Decl. ¶ 43.) Furthermore, if a dosage form escapes from the stomach, there is no further opportunity to prevent it from passing into the colon while still containing drug, which the specification says raises a number of problems. (See '475 patent, 2:21-33.)

To overcome these problems, the specification states:

> For highly soluble drugs, the swelling of the polymeric matrix thus achieves two objectives – (i) the tablet swells to a size large enough to cause it to be retained in the stomach during the fed mode, and (ii) it retards the rate of diffusion of the highly soluble drug long enough to provide multi-hour, controlled delivery of the drug into the stomach. For [other] drugs . . ., the swelling of the polymeric matrix (i) renders the matrix sufficiently large to cause retention in the stomach during the fed mode, and (ii) localizes the release of the drug to the stomach and small intestine . . . .

('475 patent, 6:18-32.)

In fact, the claimed dosage forms are designed to resist being expelled from the stomach.

(See, e.g., id. at 9:1-21 (explaining that the drug matrices are designed to "promote[] their retention in the stomach"), 11:63-12:4 (explaining that the dosage form is designed to swell to a size to remain in the stomach).) These design features to keep the claimed dosage form in the stomach make sense in view of the problems that the patentee stated it was trying to overcome – i.e., having drug-containing dosage forms travel into the colon. (Lowman Decl. ¶ 45.)

The disclosure provided in the '927 patent family further confirms that the gastric retained dosage form must remain in the stomach for the duration of drug delivery to allow the drug to be absorbed adequately in the preferred region of absorption. The '927 patent family disclosure provides that "the gastric retained dosage form is particularly beneficial for delivery of gabapentin due to its prolonged transit in the upper gastrointestinal tract, which allows the drug to be absorbed adequately in the preferred region of absorption." ('927 patent, 2:16-20.)

The prosecution history of the '927 patent further supports Defendants' proposed construction. (See Lowman Decl. ¶ 47.) When faced with an objection that the claims were obvious over the prior art, the patentee argued that the claims were distinguishable over the prior art because, unlike the prior art dosage form, the claimed dosage form "swells on its exterior when exposed to water in the stomach[, which] increases retention of the dosage form in the stomach *for the duration of drug delivery*." (Ex. 12a at 15 (emphasis added).) Thus, consistent with the specification, the patentee clearly stated that the dosage form must be retained in the stomach for the duration of drug delivery. (Lowman Decl. ¶ 47.) Defendants' proposed construction is thus supported by the intrinsic evidence.

Depomed, on the other hand, asks the Court to leave the construction of the term vague by adopting the prior construction's language of "several hours." This vague construction is contrary to the purpose of claim construction, which is to provide clarity. U.S. Surgical, 103

F.3d at 1568. Such a construction will only invite further disputes as to the number of hours that are sufficient to meet the "several hours" requirement. On the other hand, there is a more specific construction that is supported by the intrinsic evidence as described above that provides a clear guidepost to the factfinder. Depomed's proposed constructions should be rejected.

Furthermore, Depomed argues that "gastric retained" (claim term no. 4) does not need construction. In view of the Parties' dispute concerning the other related terms "gastric retention" and "retention in the stomach," however, "gastric retained" should be similarly construed in order to avoid ambiguity and prevent further disputes. See U.S. Surgical, 103 F.3d at 1568. Depomed's proposal to refrain from construing claim term no. 4 should be rejected.

B. Retention in the Stomach Is Independent of the Fed Mode

Claim term nos. 4 and 14 are semantically different from claim term nos. 12, 13, 15 and 16 with respect to the "fed mode" being induced. With respect to the asserted '927 patent claims (claim term nos. 4 and 14), the claims require the step of "administering . . . gabapentin . . . dispersed in a *gastric retained dosage form* to the mammal *in which a fed mode has been induced*." ('927 patent, 12:38-43 (emphasis added).) The syntax of this sentence makes clear that gastric retention of the dosage form is independent of induction of the fed mode. In contrast, the claims of the '475, '280, '989 and '756 patents (claim term nos. 12, 13, 15, 16) each require gastric retention of the claimed dosage form "during the fed mode" or "in . . . a fed mode," which makes clear that the gastric retention is dependent on the fed mode being first induced. Because of this difference in claim language, Defendants' proposed construction of claim term nos. 4 and 14 clarify that the retention of the swollen dosage form in the stomach is independent of the consumption of food, which would trigger the fed mode. (See '475 patent, 11:53-54 ("The postprandial or fed mode is induced by food ingestion . . . ."); Lowman Decl. ¶ 48.) See Kara

Tech. Inc. v. Stamps.com Inc., 582 F.3d 1341, 1347 (Fed. Cir. 2009) (each claim in a patent family is presumed to be of different scope).

Consistent with this, the specification of the '927 patent family refers to certain dosage forms as gastric retained dosages, and these dosages do not require administration during the fed mode. (See, e.g., '927 patent, 5:52-57 (multi-layer tablet with a band)[12]; Lowman Decl. ¶ 49.) Thus, the specification describes that the claimed dosage form can be retained in the stomach independent of the fed mode first being induced. (Lowman Decl. ¶ 49.)

The prosecution history also supports this construction. (Lowman Decl. ¶ 50.) When faced with an obviousness objection over the prior art, the patentee added "in which a fed mode has been induced" to the claim limitation reciting "a gastric retained dosage form" to differentiate the claimed dosage form. (Ex. 12b at 4.) Adding the "fed mode" reference in the claim would not have been necessary if "gastric retained dosage form" was understood to always refer to a dosage form administered in the fed mode.[13] Thus, the prosecution history also demonstrates that the ability of the claimed dosage form to be gastric retained is independent from the consumption of food. (Lowman Decl. ¶ 50.)

Depomed argues that the Court should adopt the prior construction of "attaining a size large enough to promote retention in the stomach" from the Sun case. The Court did not, however, construe a term "attaining a size large enough to promote retention in the stomach" in the Sun case, and neither did Judge Hamilton in the Lupin case. (See generally Exs. 14 & 15.)

[12] The referenced patent indicates that the claimed invention purports to satisfy the goal of providing a sustained delivery device that is "able to remain in the stomach, even during a fasting state in which IMMC is present, for a prolonged period." (Ex. 17, 4:55-5:9.)

[13] Applicant remarked that the "fed mode is irrelevant with respect to swelling the dosage form." Rather, "[i]n fed mode, the pylorus closes, allowing more time for the dosage form to swell and adhere in the stomach." (Ex. 12a at 16.)

The only terms at issue contained the phrase "during the fed mode" at the end of the phrase.[14] (Ex. 15 at 15; Ex. 14 at 7, ll. 7-13.) Depomed's proposed construction should thus be rejected.

6. "GAS GENERATING AGENT" IN THE '927 PATENT[15]

Term No.	Claim Language	Defendants' Proposed Construction	Depomed's Proposed Construction
35	gas generating agent	"an agent capable of releasing carbon dioxide or nitrogen"	Plain and ordinary meaning; does not require construction

The specification of the '927 patent discloses a dosage form with a gas generating agent as having "one component that expands on contact with gastric juice and contains an *agent* capable of releasing carbon dioxide or nitrogen, gabapentin or a pharmaceutically acceptable salt thereof." ('927 patent, 6:29-35 (emphasis added).) No gases other than carbon dioxide or nitrogen are described in the '927 patent. Thus, the patentee made clear that a "gas generating agent" is "an agent capable of releasing carbon dioxide or nitrogen." (Lowman Decl. ¶ 53.)

The specification of the '927 patent cites to and purports to incorporate by reference the teachings of U.S. Patent No. 4,996,058 ("the '058 patent") (Ex. 18) for the purpose of further describing a "gas generating agent." ('927 patent, 5:57-62, 6:29-49, 11:33-38.) Depomed thus cannot dispute that the '058 patent is part of the relevant intrinsic evidence for the meaning of the term. See Cook Biotech Inc. v. Acell, Inc., 460 F.3d 1365, 1375-78 (Fed. Cir. 2006) (reversing construction that was contradicted by prior art that was incorporated by reference in specification). The dosage form disclosed in the '058 patent includes a component that expands on contact with body fluid and that contains a substance that generates a "blowing agent," i.e., gas, "especially carbon dioxide or nitrogen." ('058 patent, 2:14-20, 3:26-50.) Suitable substances for generating gas are disclosed as those capable of releasing carbon dioxide or

[14] In fact, the Sun case parties stipulated to adopt the construction from the Lupin case.

[15] This disputed claim term is found in claims 28 and 43 of the '927 patent.

nitrogen (see id. at 3:26-50), and each of the three independent claims of the '058 patent recites an "agent" capable of releasing carbon dioxide (claims 2 and 3) or "carbon dioxide or nitrogen" (claim 1). (See id. at 12:62-14:13). As with the '927 patent, no gases other than carbon dioxide or nitrogen are disclosed. (Lowman Decl. ¶ 54.)

By disagreeing with Defendants' proposed construction, Depomed leaves open the potential for future disputes over the term. See U.S. Surgical, 103 F.3d at 1568. Depomed's construction should thus be rejected. (See Lowman Decl. ¶¶ 53-55.)

7. "BILAYERED OR MULTILAYERED ADHESIVE TABLET" IN THE '927 PATENT[16]

Term No.	Claim Language	Defendants' Proposed Construction	Depomed's Proposed Construction
36	bilayered or multilayered adhesive tablet	a tablet having only one gabapentin/polymer matrix layer and one or more additional layers	Plain and ordinary meaning; does not require construction

Defendants' construction of "bilayered or multilayered adhesive tablet" is consistent with the intrinsic evidence of the '927 patent. The term "bilayered or multilayered adhesive tablet" appears in claims 30 and 45, which depend from claims 17 and 33, respectively. Both claims 17 and 33 require a *single* polymer matrix that contains a swellable polymer that releases gabapentin through diffusion. (See '927 patent, 12:37-51, 13:16-17, 13:25-39, 14:4-5.) While dependent claims 30 and 45 require at least two layers, a person of ordinary skill in the art would understand from the claim language "*single* polymer matrix" that only one of the layers of the "bilayered or multilayered adhesive tablet" is the gabapentin/polymer matrix layer. (Lowman Decl. ¶ 55.) See Phillips, 415 F.3d at 1313.

The specification of the '927 patent further supports Defendants' proposed construction. (See Lowman Decl. ¶ 57.) For example, where the specification describes a bilayer tablet, it

[16] This disputed claim term is found in claims 30 and 45 of the '927 patent.

states that "a bi-layer tablet releases gabapentin to the upper gastrointestinal tract from an active containing layer, while the other layer is a swelling or floating layer." ('927 patent, 7:6-12.) When read through the lens of the claims – which require that the gabapentin is released by diffusion through a "single polymer matrix" – the specification clearly indicates that a bilayered or multilayered tablet contains a single gabapentin-polymer matrix layer and at least one additional layer that is not a gabapentin-polymer matrix layer. (Lowman Decl. ¶ 57.)

Further, the '927 patent explains that details of the embodiment that is a bilayer tablet may be found in U.S. Patent No. 5,232,704 ("the '704 patent") (Ex. 19), which the '927 patent specification purports to incorporate by reference. (See '927 patent, 5:52-62, 11:32-38.) Thus, the patentee cannot dispute that the '704 patent provides relevant description regarding the meaning of "bi-layer tablet." Cook, 460 F.3d at 1375-78. The '704 patent discloses a bilayer dosage form wherein one layer is a drug release layer containing the drug in a polymer matrix and the other layer is a buoyant or floating layer. (See '704 patent, Abstract, 2:46-60, 2:65-3:7, 4:55-63, 22:65-23:19.) The '704 patent specification states that, "by designing a bilayer floating capsule wherein the optimized buoyancy formulation layer is separated from the drug release formulation layer, a greater flexibility of release profile adjustments is obtained." (Id. at 7:26-30.) Consistent with the specification, the '704 patent claims make clear that only one layer of the dosage form, i.e., the "drug release layer," contains drug, while the other layer is a "floating layer" that provides buoyancy to the bilayer formulation. (See, e.g., id. at 22:65-23:8; Lowman Decl. ¶ 58.)

Finally, the prosecution history of the '927 patent supports the Defendants' proposed construction. In overcoming an obviousness objection, the patentee distinguished the prior art, arguing that, "[i]n contrast to Shell, Applicant's claimed dosage form is comprised of a single

polymer matrix with drug dispersed therein." (Ex. 12b at 20-21 (describing Shell as requiring "a *plurality* of solid particles") (emphasis in original).) These arguments made by the patentee support Defendants' proposed construction. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582-83 (Fed. Cir. 1996) (noting that express representations made during prosecution of the patent by the patentee regarding the scope of claims "is often of critical significance in determining the meaning of the claims").

By disagreeing with Defendants' proposed construction, yet refusing to propose a concrete, alternative construction, Depomed only delays the date on which the Court will have to resolve the Parties' dispute concerning the meaning of this term, and should thus be rejected. See U.S. Surgical, 103 F.3d at 1568.

8. "DISPERSED IN A SINGLE POLYMER MATRIX" AND "DISPERSED IN A SINGLE MATRIX" IN THE '927, '989 AND '756 PATENTS[17]

Term No.	Claim Language	Defendants' Proposed Construction	Depomed's Proposed Construction
5	Dispersed in a single polymer matrix	Plain and ordinary meaning.	Dispersed in a single medium comprising polymer
6	Dispersed in a single matrix		Dispersed in a single medium

Through discussions between the Parties, it has become clear that the Parties' dispute focuses on the meaning of "single" in the claim language. This claim term does not require construction because "single" plainly means "only one," which is consistent with the intrinsic evidence.

The claims of the '927, '989 and '756 patents make clear that the claimed formulations

[17] These disputed claim terms are found in: claims 17-19, 23, 25-26, 30, 32-35, 39-43, 45, 50, 52-53, 55-56, 59 and 61-63 of the '927 patent; claims 1-7, 10-15, 19 and 20 of the '989 patent; and claims 1-12 and 15-16 of the '756 patent.

contain only one polymer matrix that contains, and controls the release of, gabapentin from the dosage form.[18] (Lowman Decl. ¶ 62.) If the claims were construed otherwise, the word "single" in the terms "dispersed in a *single* polymer matrix" and "dispersed in a *single* matrix" would have no meaning. (See e.g., '927 patent, 11:52-65; '989 patent, 12:9-12 (emphasis added); '756 patent, 12:50-53 (emphasis added); Lowman Decl. ¶ 62.) See Bicon, 441 F.3d at 950-51. Moreover, the '927 patent family specifications disclose dosage forms where gabapentin is dispersed in and released from only a single matrix containing polymer. (See e.g., '927 patent, 6:50-7:5; Lowman Decl. ¶ 63.)

The prosecution history similarly demonstrates that these two claim terms should be construed to mean that only a *single* polymer matrix of the dosage form contains gabapentin. (See Lowman Decl. ¶ 64.) During prosecution of the '927 patent, claims were rejected as obvious in light of the prior art Shell reference, which disclosed controlled-release dosage forms containing a drug dispersed within a plurality of particles containing polymer that swelled unrestrained dimensionally by imbibing water in order to retain the dosage form in the stomach. (Ex. 12d at 8-9; see also Ex. 12e at 5-6.) To overcome this rejection, the patentee amended the pending claims to explicitly add the "single polymer matrix" limitation to the claims (Ex. 12b at 2, 4, 6, 8) and repeatedly argued that this newly added limitation distinguished the claims from the Shell "plurality of particles."

For example, the patentee argued:

- "In contrast to Shell, Applicant's claimed dosage form is comprised of a single polymer matrix with drug dispersed therein. A single polymer matrix dosage form and a dosage form comprised of a plurality of particles are distinct, particularly in their drug delivery profiles after oral

[18] To be clear, the dosage form may include other matrices having other functions, but gabapentin is contained in and released from only one polymer matrix.

administration. The skilled artisan would recognize that the surface area of a *plurality* of particles must necessarily be different from the surface area of a single polymer matrix, and the release rate of drug from a collection of particles is necessarily different from that of a single polymer matrix." (Ex. 12b at 20-21 (emphases in original).)

- "[T]he claimed dosage form comprises 'a *single* polymer matrix comprising at least one swellable hydrophilic polymer that swells…'. In contrast, the dosage form described in Shell is comprised of a *plurality* of polymer particles with drug dispersed therein . . . ." (Ex. 12c at 12 (emphasis in original).)

- "Shell fails to teach of [sic] suggest a dosage form that consists of a single polymer matrix. . . . [I]n Shell the dosage form is comprised of a plurality of polymer particles, each particle loaded with a drug." (Ex. 12b at 21.)

A patentee cannot narrowly describe its invention to obtain a patent, and then seek to broaden it during claim construction. See Springs Window Fashions LP v. Novo Indus., LP, 323 F.3d 989, 995 (Fed. Cir. 2003) ("The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent.").

The plain and ordinary meaning – that gabapentin is contained in and released from only a single polymer matrix – is consistent with the intrinsic evidence and should thus be adopted by the Court. (See Lowman Decl. ¶¶ 61-65.)

9. "T_{MAX} IS AT LEAST 5.6 HOURS" IN THE '756 AND '332 PATENTS[19]

Term No.	Claim Language	Defendants' Proposed Construction	Depomed's Proposed Construction
50	wherein the time to reach maximum plasma concentration is at least 5.6 hours ±34.9%	wherein the time to reach maximum plasma concentration is not less than 3.6 to 7.6 hours	Plain and ordinary meaning; does not require construction

Defendants seek clarification that "wherein the time to reach maximum plasma concentration is at least 5.6 hours ±34.9%" means the time to reach maximum plasma

[19] This disputed claim term is found in claims 3 and 8 of the '756 patent and claims 2, 8, 13 of the '332 patent.

concentration (T_{max}) is between 3.6 hours (5.6 hours – 34.9%) and 7.6 hours (5.6 + 34.9%). Left unconstrued, this term could give rise to disputes later in litigation about which times are covered by the claims. Moreover, Defendants' construction is fully supported by the intrinsic evidence, which shows a range of T_{max} values that are within the range set forth in Defendants' proposed construction for the "GR™" (gastric retained) formulations in the Table in Example 4. ('756 patent, 11:56-12:25; Lowman Decl. ¶ 66.)

The only plausible explanation for Depomed's refusal to agree to Defendants' proposed construction of this claim term is that Depomed may try to advance a different plain and ordinary meaning at a later date to fit with its theories of the case. Depomed's attempt to leave this term open for later disputes should be rejected. See U.S. Surgical, 103 F.3d at 1568.

10. "WITHOUT LOSS IN BIOAVAILABILITY" IN THE '756 PATENT[20]

Term No.	Claim Language	Defendants' Revised, Proposed Construction	Depomed's Proposed Construction
44	without loss in bioavailability as measured by the area under the curve ($AUC_{infinity}$) as compared to the bioavailability which is achieved from an immediate release dosage form comprising the same dose of gabapentin	without any loss in bioavailability as measured by the area under the curve ($AUC_{infinity}$) as compared to the bioavailability which is achieved from an immediate release dosage form comprising the same dose of gabapentin	bioavailability as measured by the area under the curve ($AUC_{infinity}$) is at least 80% of an equal dose of gabapentin in an immediate release dosage form

Consistent with its plain and ordinary meaning as understood in light of the intrinsic evidence, the phrase "without loss in bioavailability" should be interpreted to mean without *any* loss in bioavailability. (See Lowman Decl. ¶ 68.) Any other construction would deviate from the ordinary meaning and violate the doctrine of claim differentiation. Specifically, separate claims in the earlier-filed '989 patent and later-filed '332 patent explicitly state that the gastric

[20] This disputed claim term is found in claims 1-12 of the '756 patent.

retained dosage form need only have 80% of the bioavailability of an immediate release dosage form.[21] In the '756 patent, however, the claims are more stringent than those of the '989 patent or '332 patent – they state "without loss in bioavailability." This difference in claim language between claims of the '756 patent and the '989 and '332 patents is presumed to signal a different scope in the claims. See, e.g., Kara, 582 F.3d at 1347 (noting that differences among claims in related patents can be a useful guide in understanding the meaning of particular claim terms).

The intrinsic evidence supports this construction. For example, an example in the specification of the '756 patent purports to show that one formulation (GR8 600 mg 1 x tablet) had no loss in bioavailability ($AUC_{infinity}$ in the claims) relative to an equal dose of an immediate release gabapentin (Neurontin®, 300 mg 2 x capsules). (See '756 patent, 11:41-12:38.)

Depomed seeks to improperly expand the scope of the claims by asserting that "without loss in bioavailability" means "at least 80%" of the bioavailability – i.e., permits up to a 20% loss in bioavailability. The patentee, however, used more stringent terms than "at least 80%" – it chose to use "without loss in bioavailability." To allow Depomed to now expand the scope of the claims would be unfairly prejudicial and defeat the public notice function of the claims.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court adopt their proposed constructions for the disputed claim terms.

[21] (See '989 patent, 12:36-38 ("wherein the gabapentin has a bioavailability greater than or equal to 80% of an equal dose of gabapentin in an immediate release dosage form"); see also, e.g., '332 patent, 12:19-22 ("bioavailability of gabapentin is at least 80% of that provided by the immediate release dosage form comprising an equal amount of gabapentin as measured by the area under the plasma concentration-time curve, AUC_{inf}").)

Dated: January 22, 2013

Respectfully Submitted,

/s/ Arnold B. Calmann

Arnold B. Calmann
Jeffrey Soos
Jakob B. Halpern
SAIBER LLC
One Gateway Center
10th Floor, Suite 1000
Newark, NJ 07102

Mathew J. Becker
Chad A. Landmon
Jason T. Murata
Jonas S. Zikas
Nike V. Agman
AXINN, VELTROP & HARKRIDER LLP
90 State House Square
Hartford, CT 06103
Tel: (860) 275-8100
Fax: (860) 275-8101

Attorneys for Defendants
Actavis Elizabeth LLC and Actavis, Inc.

/s/ Valentina Shenderovich

Valentina Shenderovich
SHEPPARD MULLIN LLP
30 Rockefeller Plaza
New York, NY 10112
Tel: (212) 653-8700

Bradley C. Graveline
Katie Diggins
SHEPPARD MULLIN LLP
Three First National Plaza
70 West Madison Street, 48th Floor
Chicago, IL 60602

Bridgette A. Agness
SHEPPARD MULLIN LLP
333 South Hope Street
Forty-Third Floor
Los Angeles, CA 90071
Tel: (213) 620-1780

Attorneys for Defendants
Incepta Pharmaceuticals Co. Ltd. and
Abon Pharmaceuticals, LLC

/s/ Eric I. Abraham

Eric I. Abraham
Christina L. Saveriano
HILL WALLACK LLP
202 Carnegie Center
Princeton, NJ 08540
Tel: (609) 924-0808
Fax: (609) 452-1888

Michael J. Gaertner
Scott B. Feder
Kevin M. Nelson
Amanda K. Kelly
Andy J. Miller
LOCKE LORD LLP
111 South Wacker Drive
Chicago, IL 60606
Tel: (312) 443-1890

Fax: (312) 896-6674

Attorneys for Defendants
Zydus Pharmaceuticals (USA), Inc. and
Cadila Healthcare Limited